

## § 184.1976

0.04 percent for hard candy as defined in §170.3(n)(25) of this chapter; 0.1 percent for soft candy as defined in §170.3(n)(38) of this chapter; and 0.002 percent or less for all other food categories.

[43 FR 14644, Apr. 7, 1978, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 49536, Dec. 3, 1985]

## § 184.1976 Candelilla wax.

(a) Candelilla wax (CAS Reg. No. 8006-44-8) is obtained from the candelilla plant. It is a hard, yellowish-brown, opaque-to-translucent wax. Candelilla wax is prepared by immersing the plants in boiling water containing sulfuric acid and skimming off the wax that rises to the surface. It is composed of about 50 percent hydrocarbons with smaller amounts of esters and free acids.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 67, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant as defined in §170.3(o)(18) of this chapter and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: in chewing gum as defined in §170.3(n)(6) of this chapter and in hard candy as defined in §170.3(n)(25) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51617, Nov. 10, 1983]

## 21 CFR Ch. I (4-1-02 Edition)

## § 184.1978 Carnauba wax.

(a) Carnauba wax (CAS Reg. No. 008-015-869) is obtained from the leaves and buds of the Brazilian wax palm *Copernicia cerifera* Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water. It is marketed in five grades designated No. 1 through No. 5. Grades No. 4 and No. 5 represent the bulk of the commercial trade volume. These commercial grades consist chiefly of C<sub>24</sub> to C<sub>32</sub> normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking agent as defined §170.3(o)(1) of this chapter; as a formulation aid as defined in §170.3(o)(14) of this chapter; as a lubricant and release agent as defined in §170.3(o)(18) of this chapter; and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in §170.3(n)(1) of this chapter; chewing gum as defined in §170.3(n)(6) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; fresh fruits and fruit juices as defined in §170.3(n)(16) of this chapter; gravies and sauces as defined in §170.3(n)(24) of this chapter; processed fruits and fruit juices as defined in §170.3(n)(35) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51147, Nov. 7, 1983]

**§ 184.1979 Whey.**

(a)(1) *Whey*. Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking. Whey obtained from a procedure, in which a significant amount of lactose is converted to lactic acid, or from the curd formation by direct acidification of milk, is known as acid whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Sweet whey has a maximum titratable acidity of not more than 0.16 percent, calculated as lactic acid, and an alkalinity of ash of not more than 225 milliliters of 0.1N hydrochloric acid per 100 grams. The acidity of whey, sweet or acid, may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(2) *Concentrated whey*. Concentrated whey is the liquid substance obtained by the partial removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(3) *Dry or dried whey*. Dry or dried whey is the dry substance obtained by the removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(b) The ingredients meet the following specifications:

(1) The analysis of whey, concentrated whey, and dry (dried) whey, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Admin-

istration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) Protein content, 10 to 15 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled "Total Nitrogen—Official Final Action" under the heading "Total Solids," or in section 16.193 (dry sample), entitled "Kjeldahl Method" under the heading "Protein—Official Final Action."

(ii) Fat content, 0.2 to 2.0 percent—as determined by the methods prescribed in section 16.059 (liquid sample), "Reese-Gottlieb Method [Reference Method] (11)—Official Final Action" under the heading "Fat," or in section 16.199 (dry sample), entitled "Fat in Dried Milk (45)—Official Final Action."

(iii) Ash content, 7 to 14 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled "Ash (5)—Official Final Action" under the heading "Total Solids," or in section 16.196 (dry sample), entitled "Ash—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(iv) Lactose content, 61 to 75 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled "Gravimetric Method—Official Final Action" under the heading "Lactose," or in section 31.061 (dry sample), entitled "Lane-Eynon General Volumetric Method" under the heading "Lactose—Chemical Methods—Official Final Action."

(v) Moisture content, 1 to 8 percent—as determined by the methods prescribed in section 16.192, entitled "Moisture (41)—Official Final Action" under the heading "Dried Milk, Nonfat Dry Milk, and Malted Milk."

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled "Method I—Official Final Action" under the heading "Total Solids."

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled "Acidity (2)—Official Final Action" under the heading "Milk," or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10